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Remarks

Claims 1 through 21 remain pending in the application.

Overall, the claims as amended are directed towards devices for performing CPR. No motivation exists to modify devices and methods for providing artificial respiration to achieve the claimed limitations due to the unpredictable hemodynamic effect of modifying devices for compressing a patient. Thus, no one would be motivated to combine or otherwise modify the cited artificial respiration references. Thus, claims 1 through 13, 15 through 18, 20 and 21 are non-obvious. (Claims 14 and 19 are not anticipated or obvious for the reasons described below.)

Now turning to the individual rejections, the Office Action rejects claim 1 as obvious over Meister, Artificial Respirator, U.S. Patent 2,486,667 (Nov. 1, 1949), in view of Bastyr et al., Orthopedic Brace Having A Pneumatic Pad And Associated Pump, U.S. Patent 5,520,622 (May 28, 1996) under the assertion that Meister teaches a band, a driver mechanism, a cushion and an automatic controller inside the driver mechanism to control the timing of compression cycles, cushions attached to the inside surface of the band disposed between the chest of the patient and the band, that Bastyr teaches fluid-filled cushion pads, and that it would have been obvious to modify Meister to use fluid filled cushions as taught by Bastyr as an obvious equivalent to a foam cushion and to provide a soft cushion having a hardness and size that is variable as taught by Bastyr.

The proposed combination does not meet the limitations of claim 1 as amended. Meister does not show or suggest a method of performing CPR or a device capable of performing CPR, Meister does not show a controller programmed to constrict the belt to a tightness sufficient to perform CPR and Meister does not show a

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controller programmed to contract the band at a rate sufficient to perform CPR. Bastyr adds nothing to the proposed combination with respect to these limitations. Thus, the combination of Meister and Bastyr does not result in claim 1 as amended.

Furthermore, if Meister were used as a device for performing CPR, it would have had an unpredictable hemodynamic effect since it is not possible to know in advance how a particular new device will affect hemodynamics until the new device is tested. This fact negates any motivation for anyone of ordinary skill to modify Meister or the combination of Meister and Bastyr to achieve the claimed limitations as amended. In addition, the issue of comfort is wholly negated in any device for performing CPR since the patient is unconscious — comfort is not only a non-issue for the patient, but is also completely irrelevant to the patient's survival. The AHA guidelines provide that CPR should continue even if ribs are broken and the lungs are being repeatedly punctured. Thus, the amended claims are non-obvious over the proposed combination.

In addition, Meister is non-analogous art to the claimed inventions. Meister is in the art of devices and methods for assisting respiration. The claimed inventions are in the art of devices and methods for performing CPR. These arts are unrelated to each other given the vastly different requirements for the two procedures. Artificial respiration requires relatively slow compressions that are insufficient to produce enough blood flow to keep a cardiac arrest patient alive. CPR requires strong, high-frequency compressions that provide hemodynamic flow. The procedures and devices for the two kinds of treatments are inherently different. Thus, Meister is not in the same field as the claims as amended.

Furthermore, Meister is not reasonably related to the problem to be solved; namely, to create devices and methods for safely compressing the chest of a patient in a manner sufficient to

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perform CPR while also improving hemodynamic flow over other CPR devices and methods. Thus, Meister is non-analogous art to the claims as amended. Accordingly, Applicant requests that the rejection of claim 1 be withdrawn and the claim allowed.

Similarly, Bastyr is non-analogous art to the claimed inventions. Bastyr shows a knee brace with pads and is in the art of orthopedic support devices. The claims are directed to devices and methods for performing CPR. Thus, Bastyr is not in the same field as the claimed inventions as amended. In addition, Bastyr is not reasonably related to the problem to be solved; namely, to create devices and methods for safely compressing the chest of a patient in a manner sufficient to perform CPR while also improving hemodynamic flow over other CPR devices and methods. (Contrary to the assertion of the Office Action, the problem to be solved is not the composition of the pads shown in Meister.) Thus, Bastyr is non-analogous art to the claims as amended. Accordingly, Applicant requests that the rejection of claim 1 be withdrawn and the claim allowed.

In its response to arguments, the Office Action appears to assert that the relevant art is "providing cushions between the band and the patient to protect the patient from injury." This statement does not describe the art in which the claims as amended are classified, nor does the statement reflect the problem to be solved. The claims as amended are in the art of devices and methods for performing CPR and the problem to be solved is to create devices and methods for compressing the chest of a patient in a manner sufficient to perform CPR while also improving hemodynamic flow over other CPR devices and methods. In the case of Meister and Bastyr, neither reference is relevant to CPR and thus both references are non-analogous art to the claims as amended.

In addition, had the proposed combination been obvious, then it would already have been disclosed in the prior art. Meister is

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over 50 years old. Fluid-filled pads such as those provided in Bastyr have existed at least that long. Given the stark reality of tens of millions of deaths from cardiac arrest over those years, a strong financial and humanitarian motivation has existed to provide a device to save victims of cardiac arrest. Hundreds of thousands of highly trained medical professionals have treated these patients and failed to show or suggest a device that meets the claimed limitations as amended. Thus, if the claimed invention were obvious in view of Meister and Bastyr, then the claimed device would have been on the market for many years. The failure of anyone to suggest, build or market the claimed device for over 50 years indicates that there is no motivation to combine or modify the references. That same failure also shows that Meister does not work as a chest compression device. Accordingly, claim 1 as amended is non-obvious.

In addition, the Office Action assertion that it is an obvious alternative to use a foam cushion versus a fluid filled cushion is incorrect. Changing the composition of the cushion would have had an unpredictable hemodynamic effect which could not be verified except by experiment. Thus, the foam-filled and fluid-filled pads are not equivalent. The Examiner provides no evidence that they are interchangeable and there is, to Applicant's knowledge, no indication in the prior art that fluid filled pads would have a beneficial hemodynamic effect.

Given the dire consequences of failing to produce a beneficial hemodynamic effect, those of ordinary skill would be motivated to avoid modifying any reference without experimental data indicating that a device or method should be modified. (The Examiner has failed to provide any prior art reference that shows the improved hemodynamic effects of using a fluid-filled pad vis-à-vis a foam pad.) Thus, claim 1 as amended is non-obvious.

In addition, Meister teaches away from the claims as amended. Based on Applicant's experiments, if Meister's belt were moved up

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around the patient's chest, then Meister would produce the opposite of the desired result -- decreased hemodynamic performance. Meister would compress the patient's ribs preferentially with respect to the sternum, thus squeezing the sides of the chest. Preferentially squeezing the sides of the chest produces less blood flow than anterior-posterior compressions (which result in significant blood flow). By directing force against the lateral portions of the rib cage, if modified for use above the abdomen, Meister would accomplish lateral compression of the ribcage, thereby lifting the sternum and leaving the heart uncompressed. Thus, all the power expended on compression would be wasted in ineffectual deformation of the chest without significant hemodynamic effect. The proposed combination would result in a non-working device, and so one skilled in the art would have been motivated to avoid the modifications suggested by the Examiner if they understood the mechanical reaction of the chest to compressions, and its effects on blood flow (if not, they might have made an unmotivated modification which would have proved ineffective in producing blood flow). Thus the claims as amended are non-obvious in view of Meister.

Moreover, squeezing the sides of the chest would substantially increase the probability that the patient's ribs would break during compressions, possibly causing severe internal damage. One of ordinary skill would be motivated to avoid this outcome and thus avoid Meister when designing a device or method for performing chest compressions, especially in the light of a probable decrease in hemodynamic performance. Accordingly, Meister teaches away from claim 1 as amended.

In its response to arguments, the Office Action states that, "whether or not the prior art is as efficient as the instant invention is not relevant...that the prior art anticipates the claim limitations is." The Office Action misapprehends Applicant's

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argument. No one would be motivated to modify the references as proposed because creating a less efficient CPR device would reduce patient survival. Thus, those of ordinary skill in the art would be motivated to avoid modifying Meister. Since Meister must be modified to meet the claimed limitations as amended and since the rejection is an obviousness rejection, arguments that demonstrate that there exist motivations to avoid modifying the cited art are appropriate and, in this case, forceful.

In its response to arguments the Office Action also states that "the exact location of the device during use is dependent on practical considerations of intended use." There was no motivation to use the devices for the intended use, and thus the "practical considerations" are clearly non-obvious. Moreover, it is not sufficient to merely state without support that moving pads or belts around is obvious or based on "practical considerations," especially given the dire consequences of creating devices that reduce patient survival. Thus, the claims as amended are non-obvious.

Moreover, the statement does not meet the mandated test for obviousness. Outdated maxims, such as "practical considerations of intended use," "equivalent alternatives" and "design choice" have been replaced by the mandated test for patentability given in Graham v. John Deere. The Examiner must provide a valid motivation for why those of ordinary skill would modify Meister. In the case of the claims as amended, this is simply not possible given the unpredictable hemodynamic effect of modifying devices not intended for CPR. (Furthermore, the proposed motivation of improving comfort in the patient is irrelevant to the claims.)

In its response to arguments, the Office Action states that Meister teaches that the placement of the cushions along the band is adjustable so that they can be placed in proper position. Adjusting placement of the cushions around the

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chest to achieve the most effective results would be obvious to one of ordinary skill in the art.

Meister does not teach moving his band around the chest and does not teach a device for performing CPR. Adjusting the cushions may be appropriate for helping a patient breathe, but it is impossible to know a priori whether moving the cushions would improve hemodynamic flow. Thus, Meister does not show adjusting the pads in a way that would beneficially accomplish CPR as claimed.

In its response to arguments, the Office Action states that Meister does compress the chest, citing that Meister discloses that his belt is adapted to encircle the "chest diaphragm" of the patient. Applicant is unsure as to the meaning of this term, though Applicant maintains that Meister does not compress the patient's chest. Meister compresses the abdomen and the diaphragm and would not compress the chest because doing so would be counter-productive. If the chest were compressed, diaphragm would not be squeezed well enough to help the patient breathe. Thus, there would be no motivation to move the belt up around the patient's chest to constrict the chest. (This same reasoning applies with reference to the rejections based on Chang, as further discussed below.) Accordingly, claim 1 as amended is non-obvious.

The Office Action also states that "as long as the Meister band is capable of being placed on the chest of the patient, it anticipates the claimed limitations." In order to achieve the limitations of the claims as amended, Meister must be modified. As pointed out above, no one would be motivated to so modify Meister; thus, the claims as amended are non-obvious.

The Office Action rejects claims 2 through 13 as obvious over Chang, Method and Apparatus for Applying High Frequency Extrathoracic Induced Breathing, Canadian Patent 1,225,889 (Aug. 25, 1987), in view of Meister, under the assertion that Chang

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teaches a band including a plurality of fluid receiving cells and a reciprocating pump for automatically supplying fluid to the cells, that Meister teaches a device for compressing the chest and the need for providing compression pads between the band and the chest, and that it would have been obvious to modify Chang to provide compression pads disposed between the chest and the band as taught by Meister to enhance respiration producing action of the device. Regarding claims 3, 6, 9 and 12, the Office Action states that it would have been obvious to provide a sealed cushion so that moisture from the patient doesn't saturate the cushion. Regarding claims 5, 8 and 11, the Office Action states that the two fluid-receiving cells are in fluid communication with each other because the tubes shown in Chang are linked together and that the pressure will always be the same in both cells. The Office Action also asserts that it is obvious to apply cushions between the patient and a band that is being constricted around the chest of the patient as dependent on practical considerations, that perhaps local injuries on the chest of the patient would preclude a band compressing the wound site and that placing cushions between the band and the chest would be within the realm of the artisan of ordinary skill.

The proposed combination does not meet the limitations of the claims as amended. Both Chang and Meister show devices for performing artificial respiration and do not show the claimed limitations directed to rate of chest compressions or the strength of chest compressions. Thus, the proposed combination does not result in the claimed inventions as amended.

Moreover, the Office Action statements that providing cushions around the chest are dependent upon practical considerations and are well within the realm of the ordinary artisan are incorrect. As discussed in relation to the rejections over Meister and Bastyr, the unpredictable hemodynamic effect of modifying devices for performing CPR, much less devices for



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providing artificial respiration, militate that no one of ordinary skill would be motivated to modify the references. Thus, the claims as amended are non-obvious.

In addition, the Office Action statement that "perhaps local injuries on the chest of the patient would preclude a band compressing the wound site" is not understood. Moreover, the statement appears to be hypothetical to such a degree that the statement is insufficient to provide a motivation to combine the references.

In relation to claims 3, 6, 9 and 12, the Office Action statement that "it would have been obvious to provide a sealed cushion so that moisture from the patient does not saturate the cushion" is incorrect. There is no moisture from the patient. Even if there were, changing the moisture content, or the lack thereof, in the pad or band could have an unpredictable hemodynamic effect. Thus, the statement would not be accepted by one of ordinary skill in the art as a motivation to modify the references to result in the claimed inventions as amended. Accordingly, the claims as amended are non-obvious.

In relation to claims 8 and 11, the Office Action statement that "the two fluid receiving cells are in fluid communication with each other because the tubes are linked together" does not address the limitations in claims 8 and 11 that require a manifold. Neither Chang nor Meister shows a manifold. The fact that Chang shows the fluid cells being linked by a tube is not sufficient to show the structural limitation of a manifold. Thus, the proposed combination does not result in the inventions of claims 8 and 11.

The Office Action rejects claims 14 and 19 as anticipated by Baldwin II, Method and Apparatus for Performing Cardio-pulmonary Resuscitation with Active Reshaping of the Chest, U.S. Patent 5,743,864 (Apr. 28, 1998) under the assertion that Baldwin shows a

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band extending around the chest of a patient, that the piston is operably connected to the band for contracting the band about the chest of the patient as shown in Figures 5 and 6, that a fluid filled cushion (item 32) is disposed between the chest of the patient and the band, that an automatic controller controls the operation of the driver mechanism and that the cushion is sized and dimensioned to cover substantially the entire anterior and posterior portion of the chest.

Baldwin does not anticipate claims 14 and 19 since Baldwin, contrary to the Office Action assertions, does not teach at least two of the limitations of the claims. Baldwin does not teach that the band (his collar, item 24') contracts and Baldwin does not teach that the collar is sized and dimensioned to cover substantially the entire anterior and posterior portions of the chest.

Baldwin does not teach contracting the collar. Baldwin instead drives his piston upwardly and downwardly, which in turn pulls and pushes on the collar. Although this action does squeeze the sides of the chest, it does not contract the collar itself. Baldwin specifically teaches that his collar is made of a non-extensible material; thus, the circumference of his collar cannot contract. If his collar were extensible, then his device would not operate as described, thus negating the function of his invention. This negates any motivation to modify Baldwin. On the other hand, Applicant's claims require that the band be contracted. The specification provides that contracting the band shortens the actual circumference of the band. (See page 6, lines 8 through 17 and page 8, lines 7 through 13.) Baldwin does not teach or suggest this limitation, but rather teaches that his collar does not contract. Thus, Baldwin does not anticipate claims 14 and 19.

In addition, Baldwin does not teach that the band is sized and dimensioned to cover substantially the entire anterior portion

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of the chest of the patient. Baldwin does state that he restrains the "circumference of the thoracic cavity" and that the collar "surrounds and conforms to the contour of the chest," though Baldwin provides no other disclosure regarding the size and dimensions of the band. Moreover, Baldwin's collar accomplishes both of the above descriptions without covering substantially the entire anterior portion of the chest. Thus, one would turn to the figures to gauge the relative size of the collar. The figures all show that the collar does not cover substantially the entire anterior portion of the chest. Instead, the collar is relatively narrow. For example, figures 1, 4 and 7 all show a number of ribs inferior to the collar, show that the collar does not extend into the area just above the xiphoid process and show that the collar extends from a point inferior of the patient's armpits. From the Baldwin figures, one can see that Baldwin does not teach a collar or band that covers substantially the entire anterior portion of the patient's chest. Given the lack of other disclosure in Baldwin regarding the size of the collar, Baldwin therefore does not anticipate claims 14 and 19.

The Office Action rejects claims 2, 5, 8, 11, 15 through 18, 20 and 21 as obvious over Chang in view of Cook, Respiration Appliance, U.S. Patent 3,503,388 (Mar. 31, 1970) in view of Bastyr under the assertion that Cook teaches that for the comfort of the patient a cushion is used around the inside of the band, that the cushion extends all the way around the inside band and therefore covers substantially the entire portion of the chest of the patient, that Bastyr teaches fluid filled cushions are more desirable and an obvious equivalent alternative to foam cushions and that it would have been obvious to modify Chang to include a cushion on the inside of the band as taught by Cook for the best comfort of the patient and to use fluid filled cushions as taught by Bastyr as an obvious equivalent to foam.

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The proposed combination does not result in the claims as amended. All of the references are related to devices for performing artificial respiration and, as pointed out above, no one would be motivated to modify the references to create devices that perform CPR. Thus, the claims as amended are non-obvious.

In addition, the Office Action appears to be citing Cook for the proposition that patient comfort is a motivation for adding pads to the combination of Meister and Bastyr. While such a motivation may apply to devices, such as Cook's, for aiding respiration, such a motivation is wholly irrelevant to CPR and to the art of designing devices for performing CPR. Thus, the claims as amended are non-obvious.

In its response to arguments, the Office Action states that "Applicant's position [that Meister provides no indication that adding cushions would work in a CPR device] is not understood since Meister already teaches adding cushions to the device." With respect to the claims as amended, Meister is not a CPR device and is ineffective as a CPR device. Thus, Meister does not teach that adding cushions would work in a CPR device. Accordingly, no one of ordinary skill would be motivated to modify Meister into a CPR device as claimed. Thus, all of the claims as amended are novel and non-obvious in view of Meister.

In its response to arguments, the Office Action states that "it is not clear how Applicant can disregard the teaching of Meister." Applicant has not disregarded the teaching of Meister. Meister teaches a device for providing artificial respiration. The Meister device may function for its recited purpose, but it is inappropriate for use as a CPR device. As described above, there is no reason to modify Meister for use as a CPR device. Thus, the claims as amended are novel and non-obvious over Meister.

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Conclusion

This response has addressed all of the Examiner's grounds for rejection. The rejections based on prior art have been traversed. Reconsideration of the rejections and allowance of the claims is requested.

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By:

*Theodore D. Fay III*

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Theodore D. Fay III  
Reg. No. 48504